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U.S. Food and Drug Administration Dockets Management Branch (HFA-305) 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Docket No. 98N-1038

Comments of The American Dietetic Association on the US Food and Drug Administration's request for comments as published in the February 17, 1999 Federal Register, Vol. 64, No. 31, pages 7834-7837: Irradiation in the Production, Processing, and Handling of Food: Advance Notice of Proposed Rulemaking.

The American Dietetic Association (ADA) represents almost 70,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well being. ADA appreciates having the opportunity to submit comments in response to the Food and Drug Administration's (FDA) advance notice of proposed rulemaking (ANPR) on irradiation and labeling requirements. The Association supports the agency's desire to gather information from interested parties as it attempts to revise labeling requirements for foods treated with ionizing radiation.

Below are excerpts from comments we recently submitted to the US Department of Agriculture's Food Safety and Inspection Service in response to a proposed rule on irradiation of meat and meat products (*Federal Register*, February 24, 1999, Vol. 64, No. 36, pages 9089-9105: Irradiation of Meat and Meat Products: Proposed Rule). Excerpts address labeling, consumer attitudes, and research/education that are also applicable to FDA's ANPR.

EXCERPTS FROM COMMENTS ADA SUBMITTED TO USDA ON APRIL 26, 1999

Note: ADA's April 26 submission to FSIS was specific to meat and poultry products; the comments below have been modified as appropriate to reflect issues raised in FDA's ANPR. ADA feels strongly that the suggestions below should apply to all other food categories for which there has been irradiation approval. We also support continued expansion of categories to include such products as fish, shellfish, eggs, produce, ready-to-eat products and mixed foods.

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As stated in our position statement on food irradiation:

It is the position of The American Dietetic Association that food irradiation is one way to enhance the safety and quality of the food supply. The ADA encourages the government, food manufacturers, food commodity groups, and qualified dietetics professionals to continue working together in educating consumers about this technology (1).

ADA firmly believes that irradiation is an important process available to control pathogens. With Hazard Analysis Critical Control Points (HACCP) plans being put in place throughout the food industry, and continued and effective consumer education efforts, irradiation could result in a meaningful reduction in the incidence of foodborne illness and significant savings in health care costs. This position is supported by numerous other organizations including the World Health Organization (WHO) (2). WHO has endorsed universal approval of foods at up to the appropriate dose necessary to achieve food safety and not compromise product integrity, taste and odor.

Consumer research also supports the use of irradiation. Focus group research conducted in 1998 shows that consumers are willing to try irradiated foods and to purchase them for their families. In this research, consumers found that food safety benefits and taste are more important than extension of shelf life (3). Research on the use of irradiation on fruits shows that consumers consistently rate irradiated fruit as equal to or better than nonirradiated fruits in appearance, freshness, and taste (4,5,6). Consumers who receive information about irradiation are less concerned about irradiation than those who did not receive the information (7). Effective educational programs can positively influence consumer-purchasing behaviors of irradiated meat (8). ADA urges government agencies and others to continue gathering important information about consumer attitudes about and preference for irradiated products, especially given the recent legislative and regulatory actions that provide for expanded use of this technology.

Expanded categories of products

ADA urges both FDA and the US Department of Agriculture to expand food category approvals as soon as possible to further enhance safety protections for consumers. Recent outbreaks due to *Listeria* in processed meat products and poultry underscore the need for additional techniques, such as irradiation, to be in place for ready-to-eat and mixture foods such as aseptic pouch items like sauces, stews and casseroles, both with and without meat. Furthermore, there are several fresh vegetable products that can be irradiated successfully to eliminate potentially harmful pathogens.

Labeling requirements

For products irradiated in their entirety, FSIS is proposing to require that package labels contain the Radura symbol and a statement indicating that the product was treated with irradiation.

- The symbol must be placed prominently and conspicuously in conjunction with the required statement.
- The statement must appear as a qualifier contiguous to the product name.
- For unpackaged meat food products irradiated in their entirety, the required logo and statement must be prominently and conspicuously displayed to purchasers.
- FSIS is proposing that, for meat food products as ingredients in multi-ingredient meat food products, the ingredient statement must reflect the inclusion of irradiated meat food product ingredients.

Note: We realize that the FDA Modernization Act, Section 403C, changed the labeling requirements for the radiation disclosure statement.

ADA supports the need for irradiated foods to be easily identifiable – both for consumers who wish to avoid them, and for those who chose them for their added value. In this light, we support continued inclusion of the wording "irradiated (name of product)" or "(name of product), treated with irradiation" on products. However, one written statement on the label regarding irradiation, in addition to the Radura symbol, should be adequate to inform consumers of the use of radiation. For example, the statement "Treated by irradiation to reduce *Salmonella* and other pathogens" should be sufficient; there is no need for dual label disclosures. ADA also supports the continued use of the Radura symbol on packaging. Consumers are becoming more familiar with the positive public health benefits associated with irradiation. Written statements and the Radura symbol are effective and serve as positive consumer education tools; any major change to labeling statements regarding irradiation could lead to consumer confusion.

ADA also urges FDA and other government agencies to continue all efforts to educate consumers about the importance of safe food handling and preparation practices of all foods, including irradiated products, after food is purchased.

Incentive labeling for irradiated meat

FSIS would consider for approval labeling statements for meat food products indicating the elimination or reduction of certain pathogens. FSIS already allows qualifiers on labels of irradiated poultry ("Treated by irradiation to reduce Salmonella and other pathogens"). FSIS sought comments on whether products could be labeled as being free of certain pathogens as a result of irradiation ("Free of E. Coli O157:H7"). FSIS sought comments on this type of incentive labeling and any other options concerning truthful labeling of irradiated meat and poultry products.

ADA supports incentive labeling such as "Treated by irradiation to reduce Salmonella and other pathogens" but does not support the proposed statement "Free of E. Coli O157:H7" or any similar statement. While irradiation can produce a product that is virtually free of a pathogen, irradiation cannot prevent post-treatment or processing contamination and/or cross contamination. Furthermore, such a statement makes it difficult for health professionals to educate consumers and food service personnel on the continued importance of safe food

handling and preparation practices. There is insufficient data on critical control points and the potential for contamination after a product leaves the processing plant where it underwent irradiation treatment, and consumers may be given a false sense of security with labeling statements such as "free of...", therefore, ADA does not support "free of..." statements.

Research/Education needs

Although the safety and efficacy of irradiation are well established, ADA urges FSIS, other government agencies, and the private sector to continue research and consumer education efforts in a number of areas.

- Research: consumer attitudes and practices surrounding irradiation with a focus on post-purchasing food handling and preparation behaviors when irradiated foods are purchased.
- Research: the ability of irradiation to destroy new and emerging microbial pathogens.
- Research: the use of irradiation in combination with other processing methods to enhance food safety or extend shelf life of all fresh or consumer packaged produce.
- Research: how best to develop and implement an infrastructure for the use of this technology. (Infrastructure refers to the building and operation of food irradiation facilities.)
- Education: consumer education to improve understanding of the relationship between food irradiation and improved public health.
- Education: continued efforts to educate consumers about the importance of food handling and preparation techniques, regardless of the processing techniques used to enhance the safety of food products.

SUMMARY

The ADA members – food and nutrition experts, have the responsibility to educate consumers about food and nutrition issues, including technologies such as food irradiation. ADA commends FDA for seeking input from interested parties as it attempts to implement provision from the Food and Drug Administration Modernization Act. We look forward to working with government agencies, food safety and nutrition professionals, consumer groups, and the food industry to continue efforts to educate the public about safe food handling and preparation, and the role of various processes and techniques, such as irradiation, in enhancing the safety of the food supply.

Sincerely,

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